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UNCLAS SECTION 01 OF 03 BRASILIA 001507

SIPDIS

DEPT FOR WHA/BSC AND EB/TPP/IPE
USTR FOR SCRONIN AND BPECK
USDOC FOR 3134/USFCS/OIO/WH/EOLSON
USDOC FOR 4332/ITA/MAC/WH/OLAC/MWARD
NSC FOR KBREIER

SENSITIVE

E.O. 12958: N/A
TAGS: KIPR ETRD ECON IPR
SUBJECT: AMBASSADOR MEETS WITH U.S. PHARMACEUTICAL FIRMS THREATENED WITH LICENSING

REF: A) BRASILIA 804, B) RIO DE JANEIRO 744, C) BRASILIA 1363

¶1. (SBU) Summary. On May 24 and 25, U.S. pharmaceutical companies Gilead Sciences, Abbott Laboratories, and Merck separately reported to Embassy on their negotiations with Brazil's Ministry of Health (MoH) over its demands that they acquiesce to licensing production of certain HIV/AIDS drugs (reftel A). Gilead reps told Ambassador they believed pressure from the USG and from Brazilian economic ministries were forcing the MoH to moderate its posture; they also expressed guarded optimism that efforts to further inform the MoH regarding potential negative economic and public health costs associated with local production, particularly through compulsory licensing, would eventually convince the MoH to abandon its insistence on licensing. Abbott reps were encouraged by the interest expressed by GoB ministries in the company's plans to invest in local production of its HIV/AIDS treatment drug, Kaletra. Meanwhile, Merck appears to be banking on a plan to manufacture certain AIDS drugs locally, but have them packaged by a GOB lab. Despite MoH demands, none of the companies have yet entered into voluntary license negotiations with the ministry. All acknowledged that the issue is as much political as economic making the eventual outcome difficult to predict. Possible movement in the Brazilian Chamber of Deputies on draft legislation that would make AIDS drugs and their production processes un-patentable would only further complicate an already complicated situation. End Summary.

Gilead Focuses on Pricing and Supply

¶2. (SBU) Gilead's International VP Joe Steele and his delegation met with Ambassador on May 24 following a new round of discussions with the Ministry of Health. Gilead had presented a proposal to the MoH designed to address the two concerns the ministry had previously identified as underlying its interest in licensing local production of Gilead's Viread (tenofovir): i.e., reliability of supply and price. While Gilead's proposal did not touch on voluntary licensing, it offered volume price reductions to achieve a MoH targeted per capsule price, and a company promise to maintain a 6-month rotating stockpile dedicated to MoH needs. Reading body language, the Gilead reps thought MoH officials were impressed with the proposal, although it was not discussed in detail. MoH officials noted their continuing interest in licensing, promising to provide Gilead with a written proposal on or before May 31.

¶3. (SBU) Steele said the tone of the MoH meeting was improved compared to their last meeting April 27; he thought the new tenor indicated a realization by the ministry that licensing, whether voluntary or compulsory, is a complex matter with potential pitfalls, not least of which would be the cost and difficulty of getting government plants to make sufficient quantities of high quality drugs. Steele thought that pressure from the USG and from Brazilian economic ministries was forcing the MoH to moderate its posture. Gilead, he added, would continue to inform the supportive ministries, such as the Ministry of Development, Industry, and Trade (MDIC), Foreign Relations (Itamaraty), and Finance (Fazenda) on his company's efforts to address MoH concerns.

¶4. (SBU) Upon receiving the MoH licensing proposal, Gilead hopes to be able to better formulate arguments for why its approach of providing a lower-priced, Gilead-manufactured product would be better for Brazil's HIV/AIDS treatment program than local production through licensing. Steele expressed guarded optimism that if a precipitous decision could be avoided, over time the company could convince the MoH that licensing the production of Viread would not be in Brazil's best interests. Ambassador committed to continuing Embassy support, but pointed out that the

political sensitivity of the issue cast doubt on whether the MoH would back down on its licensing demands.

¶5. (SBU) Drawing on its own swift transformation into one of the top biotech pharmaceutical companies, Steele said his firm would not be averse to working with the GoB to develop a plan for development of an R&D based pharmaceutical industry in Brazil. He believes GoB officials incorrectly equate production of generics with development of a "pharmaceutical industry." The latter, he emphasized, can only be built on a solid foundation for protecting intellectual property. Steele noted that Brazil is well positioned to develop a pharmaceutical industry given existing technical talent, adding that India, based on this realization, has already embarked upon such a path.

Abbott Highlights Investment Plans

¶6. (SBU) On May 25, Abbott's President in Brazil, Santiago Luque Suescun, met with Ambassador to review his company's situation. Unlike Gilead, Abbott has had a long-standing presence in Brazil. Abbott's Brazilian subsidiary was established in 1937 and currently employees 1,000 people. Abbott's response to the MoH licensing threats also differs in that it has chosen to focus on its plans to invest in Brazil for local production of the AIDS treatment drug Kaletra, rather than address pricing issues. According to Suescun, Abbott had discussed its investment plan with the MoH a number of months ago and was surprised to receive the March 14 MoH letter demanding a voluntary license for Kaletra. Abbott's response, supported by headquarters, has been to enhance the investment plan.

¶7. (SBU) Under Abbott's proposal, the new Brazilian plant would manufacture finished product (the active ingredient formulation would take place in Italy) to supply not only the Brazilian market, but also the rest of Latin America and potentially Canada. FDI is projected at USD 53.3 million between 2007 and 2009, and Abbott estimates a positive trade impact of USD 247.5 million between 2007 and ¶2011.

¶8. (SBU) Abbott has been encouraged by the interest the MoH has stated in the project (Suescun noted that MoH Infectious Disease Director Jarbas Barbosa commented three times that it was a good project); Suescun will present the details of its investment plan to officials in MDIC and Finance ministries next week. Post also suggested Suescun meet with MRE officials Antonio Simoes, in the minister's staff, and Otavio Brandelli, who has been involved in inter-ministerial discussions on the licensing issue. According to Suescun, MoH officials have not pressed Abbott to submit a pricing proposal nor have they provided them with a licensing proposal in writing. Suescun offered his best guess that, in the end, the MoH will put together the concessions it has been able to extract from each of the three target companies -- investment in local production from Abbott, substantially lower pricing from Gilead, and probably some form of local production from Merck - as a package to present to the public.

Merck - Some Form of Local Production Possible

¶9. (SBU) Finally, on May 25 the third company faced with the prospect of licensing - Merck - contacted post by telephone to outline its strategy for countering the GOB threat. Joao Sanches, Merck's Sao Paulo-based Corporate Communication Director, told us that his firm hopes to drum up support among the economic ministries for a proposal to have Merck manufacture certain AIDs drugs locally but have them packaged by a GOB-owned lab. Only after promoting this proposal with the economic ministries would Merck officially broach the issue with the MOH.

Comment

¶10. (SBU) On the positive side, the MoH is submitting to an inter-ministerial discussion with MDIC, Finance and MRE, ministries that are not supportive of its stance. It is our understanding that once negotiations with the companies are "complete," the discussion will move to the ministerial level where arguments in favor of broader, longer-term economic interests may be brought to bear. We continue to believe that to resonate with the GoB, the arguments will need to provide a sound analysis as to why compulsory licensing would be damaging to Brazil's economic and public health interests. Concomitantly, the companies will also have to demonstrate that they plan to make good-faith efforts to address the supply/pricing needs of Brazil's HIV/AIDS treatment program.

¶11. (SBU) However, the decision will ultimately be made by President Lula within a rather harsh political environment.

Dozens of NGOs have denounced the GoB for delaying in breaking the patents, delivering a mock "spine" to the Brazilian Embassy in Washington in protest on May 13. Pedro Chequer, head of Brazil's Sexually Transmitted Diseases and AIDS Program in the MoH, was reportedly in the Brazilian Chamber of Deputies the week of May 23 encouraging lawmakers to pass legislation that would make AIDS drugs and their production process un-patentable under Brazilian industrial property law. (On June 1, the Chamber's committee for constitutional and justice affairs approved the bill; the likely next stop for this measure will be the Brazilian Senate, where it will need to pass through the full range of committees and the Senate plenary.) Embassy will continue to monitor the GoB deliberations as well as to provide input through appropriate GoB interlocutors.

DANILOVICH